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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,266	08/26/2003	Howard R. Levin	3659-71	2067

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EXAMINER	
BIANCO, PATRICIA	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,266	LEVIN ET AL.	
	Examiner	Art Unit	
	Patricia M. Bianco	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 30-59* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 30-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 53-55 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truitt et al. (5,910,252) in view of Glantz (5,749,835). Truitt et al. (hereafter Truitt) teaches of a method for treating blood extracorporeal, such as by hemofiltration, hemodialysis (i.e. dialysis), or ultrafiltration. The system used to perform the treatment method comprises a catheter inserted into a vein or artery of a patient, which serves as a blood withdrawal line, and a device line (i.e. withdrawal blood tube) that supplies the withdrawn blood to the apparatus to process the blood according to a selected treatment protocol. With respect to applicant's limitation of the catheter being inserted into a large vein, great vein, or vena cava to access a reservoir of blood for continuous blood withdrawal, this step is considered to be met since the vein catheterized may be considered a large vein. The system also includes a pump connected to the withdrawal line and allows for continuous treatment by extracorporeally removing solutes from the blood. For example, in ultrafiltration the removal is excess water. The pump creates a negative pressure in the catheter, which is higher than the blood pressure in the vein or artery in which the catheter is inserted. The pump supplying negative pressure is seen to be equivalent to applying suction. With respect to claim 55, Truitt teaches that the claimed blood flow through the needle or catheter being less than 40 milliliter per minute, it is the position of the examiner that the blood treatment system of Truitt is capable of performing these rates since the system includes a programmable controller that regulates the pumps of the system. Such flow rates would have been obvious to one of ordinary sill at the time of the invention since these procedures are always modified on a patient-by-patient basis.

Glantz discloses a PICC catheter for use or placement within a peripheral vein, such as the cephalic vein, via the patient's arm. The catheter is then moved to place the tip in a desired location, such as in the superior vena cava. Glantz also teaches that, as is well known in the art, the caregiver determines the length the PICC is needed on a per patient basis (see col. 5, lines 38-63 and figures 5, 6 & 6A). With respect to the claim 54, it would have been obvious to choose a catheter having a length of 35 cm to 40 cm that may be advanced into a large or great vein since it would have been obvious to choose a length within this range, since it has been held that the discovering of an optimum value of a result effective variable involves only routine skill in the art. Furthermore, it is well known in the art, as well as taught by Glantz, that the determination of length of a PICC catheter, as well as any other catheter type used in a medical procedure, is a length determined to equal the distance between the entry site and the desired location of the catheter tip. Glantz also teaches that, as is well known in the art, the caregiver determines the length the PICC is needed on a per patient basis (see col. 5, lines 38-63 and figures 5, 6 & 6A). Therefore, this determination must be based on a patient-by-patient basis to customize the size based on the patient's anatomy and any other medical conditions that may need to be taken into consideration.

It would have been obvious to one having ordinary skill in the art, at the time of the invention, to modify the method of Truitt to include the step of inserting the catheter into a peripheral vessel, such as the cephalic artery, into the vena cava to withdraw blood into the extracorporeal circuit as the connection site. Further, it would have been obvious to substitute the catheter of Truitt with a catheter as taught by Glantz to have a

catheter that is of a length that may be advanced in a large or great vein, the that is used to be a catheter that is at least 25 cm, the catheter that is used to be not greater than 75 cm long, since it would have been obvious to one having ordinary skill in the art to use a catheter having any of these dimensions, since it has been held that the discovering of an optimum value of a result effective variable involves only routine skill in the art. Furthermore, it is well known, as taught by Glantz, that the determination of length of a catheter used in a medical procedure is a determination based on a patient-by-patient basis to customize the size based on the patient's anatomy and any other medical conditions that may need to be taken into consideration.

Claims 55- 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truitt et al. ('252) in view of Glantz ('835) as applied to claim 53 above, and further in view of Jaski et al. ("*Peripherally Inserted Veno-Venous Ultrafiltration for Rapid Treatment of Volume Overloaded Patients",* Journal of Cardiac Failure). Truitt et al. & Glantz discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the method comprises a treatment of ultrafiltration, hemofiltration, or dialysis require the catheter to be placed in the vein for a period of at least four hours and that the blood flow rate is less than 40 milliliter per minute.

Jaski et al. teaches of a removal of excess fluid by ultrafiltration via peripherally inserted venous catheter placement. The blood withdrawal rate is disclosed to be less than or equal to 40 milliliter per minute and the time of treatment was less than seven hours. A treatment time of about seven hours would result of a catheter being inserted

into a vein for at least four hours. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the method of Truitt & Glantz to remove blood from a patient to have a flow rate of less than 40 milliliter per minute and to have the treatment time, and therefore catheter placement within a vessel, for more than four hours as a matter of obvious design choice, since it has been held that the discovering of an optimum value of a result effective variable involves only routine skill in the art. Further, it is well known in the art that the flow rate and treatment time must be determined on a patient-by-patient basis to customize the size based on the patient's anatomy and any other medical conditions that may need to be taken into consideration.

Response to Arguments

Applicant's arguments filed 6/13/06 have been fully considered but they are not persuasive. Applicant argues that Truitt does not suggest or teach peripheral vein access and points to a figure that appears to show central vein access. While that is shown, the disclosure in col. 3, lines 54-59 and figure two disclose that the blood is generally withdrawn from and returned to a patient using two catheters (33,36) and that the catheters are inserted into "a vein or an artery." As set forth in the rejection, it would have been obvious to one having ordinary skill in the art, at the time of the invention, to choose to use the system & method of Truitt to include the step of inserting the catheter into a peripheral vessel to withdraw blood into the extracorporeal circuit as the connection site since it is well known in the art to withdraw blood from peripheral vessels for extracorporeal blood treatment. See U.S. Patent No. 5,470,483 as evidence

to this practice being old and well known. With respect to the argument that Glantz does not teach of inserting a catheter into a peripheral vein, Glantz was only relied upon for its teaching of using a PICC catheter. Since both Truitt and Glantz disclose using catheters, the modification of Truitt with the teachings of Glantz were an obvious matter of design choice as a substitution of parts (i.e. catheters).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571)

272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 19th, 2006

Patricia M Bianco
Primary Examiner
Art Unit 3761

PATRICIA BIANCO
PRIMARY EXAMINER